



September 5, 2000

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall brand name bearing the following statement(s) on the label and/or in the labeling:

Glucosamine Complex: [It] helps repair cartilage and promotes healthy joint function.
Glucosamine Complex contains a select combination of ingredients which help in maintaining healthy, mobile joint function and connective tissue health. Glucosamine plays an important role in the repair and maintenance of cartilage, including cartilage adversely affected by aging and physical stress. Vitamin C is essential for the production and maintenance of collagen-the main component of cartilage and key to healthy bone and cartilage formation. Essential trace minerals such as copper, manganese and zinc are also required for maintaining bone metabolism and bone density, and work to promote strong, healthy bone joints.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs

and Assistant General Counsel

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**Enclosure** 

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